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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,221	10/06/2000	Mark Rupert Tucker	HA01-P01	3673

7590 11/25/2002

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EXAMINER

NASH, BRIAN D

ART UNIT	PAPER NUMBER
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3721

DATE MAILED: 11/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/673,221

Applicant(s)

TUCKER, MARK RUPERT

Examiner

Brian D Nash

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 October 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Specification

2. The disclosure is objected to because it is unclear (page 5, line 36) how the “kiss-cut” function is provided. Additional clarification and explanation is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 4 it is not clear what is meant by “kiss-cut”.

In claim 7, the use of “and/or” is indefinite.

In claim 11, “into the or each” in line 4 is ambiguous and confusing.

In claim 19, it is unclear what is being claimed, it is unclear what the scope of the claimed invention is, and it is not clear what is meant by broad reference “to the accompanying drawings”.

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Claim 1 recites the limitation "previously open edges" in lines 25-26. There is insufficient antecedent basis for this limitation in the claim.

Claim 13 recites the limitation "sealing devices" in line 11. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claim 19 is rejected under 35 U.S.C. 102(b) as being anticipated by US 4,769,974 to Davis. Insofar as the claimed invention is understood, Davis discloses the same invention including the limitations claimed.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,769,974 to Davis in view of US 5,656,285 to Sablotsky et al. Davis discloses the invention substantially as claimed including a process having first and second (16,18) feeding strips (see

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Davis, Fig. 1), heat-sealing the strips together both longitudinally (26,28) and transversely (32,34), introducing a liquid via a tube (30) into a pouch (40); a transverse cutting step (see Davis, column 6, lines 53-55); creating two laterally adjacent pouches (see Davis, column 5, lines 62-63); flushing the pouches with a gas (see Davis, column 12, lines 48-61) via a tube (82,84,86); filling the pouches at a low pressure (see Davis, column 12, lines 15-25); and adjusting number or size of the pouches made (see Davis, column 7, lines 48-53). Davis does not disclose a first, multi-layered strip or a cutting cylinder for lateral separation of the pouches.

However, Sablotsky teaches the use of a multi-layered strip having a backing layer, an adhesive layer, and a release liner to form transdermal patches (see Sablotsky, column 3, lines 41-44) and a cutting cylinder (18,22) for the purpose of making transdermal patches in a singular and continuous mechanical motion.

Regarding claim 1, it would have been obvious to one having ordinary skill in the art to have provided Davis's process with a multi-layered strip, as taught by Sablotsky, having a backing layer, an adhesive layer, and a release liner in order to form transdermal patches.

Regarding claim 6, it would have been obvious to one having ordinary skill in the art to have provided Davis's process with a cutting cylinder, as taught by Sablotsky, for the purpose of forming transdermal patches by continuously moving a laminate web through operation and cutting at the same time.

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Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Laprade, DeVillez et al., Rudella, Williams et al., Dahlem, and Samberg are cited to show related methods.

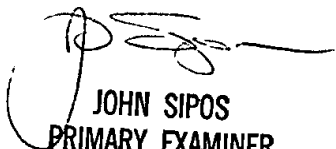
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Nash whose telephone number is (703) 305-4959. The examiner can normally be reached on Monday – Thursday from 8 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rinaldi I. Rada can be reached at (703) 308-2187. The fax number for this Group is (703) 305 -3579.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1148.

Brian D. Nash

21 November 2002


JOHN SIPOS
PRIMARY EXAMINER